

The Accellix logo features a stylized icon above the word "Accellix". The icon consists of two teardrop shapes, one red and one grey, pointing towards each other. The word "Accellix" is in a grey sans-serif font.

# Accellix

# User Manual

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## Introduction

Accellix is an affordable tabletop diagnostic device with single-use assay cartridges that does not require extensive training nor involve complex operational processes. Accellix dramatically expands access to flow cytometry capabilities by replacing previously complex testing with a user-friendly automated instrument that can be used by any medical practitioner, nursing staff, or junior lab tech on a 24/7 basis. Health practitioners get rapid results that previously required sending samples out to a central lab. Accellix eliminates that transport time, wait times at the lab, and other delays that may directly lead to degradation in patient health and effective treatment.

The Accellix platform's fast and user-friendly interface facilitates simple and reliable analysis using disposable cartridges for sepsis tests.

Accellix is mainly intended for:

- **Hospitals with time critical departments** (ICU, ER, OR, neonatal ward) - Nurses on location can run tests, eliminating long waits and queues at a central lab.
- **External/Third-party run hospital labs** - Simple, automated tests are available 24/7 to all the lab's staff, not just senior specialists. This eliminates wait time for batch processing, and tests can be run and returned quickly, proving especially useful for high-priority cases.
- **Clinics and Doctors** - Accellix drastically reduces test travel and logistics delays, resulting in quicker action and more satisfied patients.

## Intended Use

The Accellix platform may be used for a flowcytometric measurement of analytes in biological samples, using test-specific cartridges intended for use with this instrument.

## Principles of Operation

The Accellix platform, relying on the general principles of flow cytometry, combines fluidics, optics and electronics systems in order to measure and analyze optical and fluorescence characteristics of single cells. The Flow Cytometer enables complete automation of a 3 step process: biochemical sample preparation (*i.e.*, the assay), flow cytometry reading and analytical data processing.

The Accellix platform is designed to enable automatic workflow, thus it requires the user to perform only few and simple operational steps.

Following is a brief description of the mode of operation of the Accellix system:

- The user selects the assay from the menu displayed on the touchscreen.
- The user enters the patient ID
- The user places a drop of sample in the Assay Cartridge, closes the Cartridge Cap, inserts the Cartridge to the Reader Instrument, and closes the Door.

After closing the Instrument Door, the complete assay is automatically executed and the data are analyzed (i.e., the system brings the Cartridge into place, runs the assay, analyzes the results and displays the CD64 index.

- The Cartridge Handling Unit returns the Cartridge to start position and the Cartridge can be removed. The GUI prompts the user to remove the Cartridge from the Reader Instrument and to discard it as a biohazard.

## Overview of Operating Elements

The Accellix platform is a diagnostic system composed of a tabletop Flow Cytometer and a single use disposable Assay Cartridge.

The Accellix Cytometer is mainly operated through the touchscreen and attached barcode reader. Detailed description and functional specifications of the Assay Cartridge are provided in the Cartridge Instructions For Use (IFU).



**Figure 1: The Accellix platform: Flow Cytometer and Cartridge. The Assay Cartridge is shown here upon insertion into the Flow Cytometer**

## First Time Installation

1. Unpack the package and verify it contains:
  - The Accellix device
  - A power cable
  - A bar code reader
  - A biohazard bag to enable shipment of a contaminated instrument

**The original packaging is to be saved and stored in a safe place to enable its re-use for shipping back to the manufacturer for service.**

2. Place the device on a clean flat and stable surface.
3. Connect one end of the power cable to 100-220VAC 50/60Hz power source with the supplied power cable, and the other end to the power outlet at the rear of the Accellix unit. In areas with power disturbances or to ensure test completion in case of power outage it is recommended to connect the instrument to the power via an UPS that can provide 300VA or higher for amount of time of 20 minutes (not supplied with the instrument).

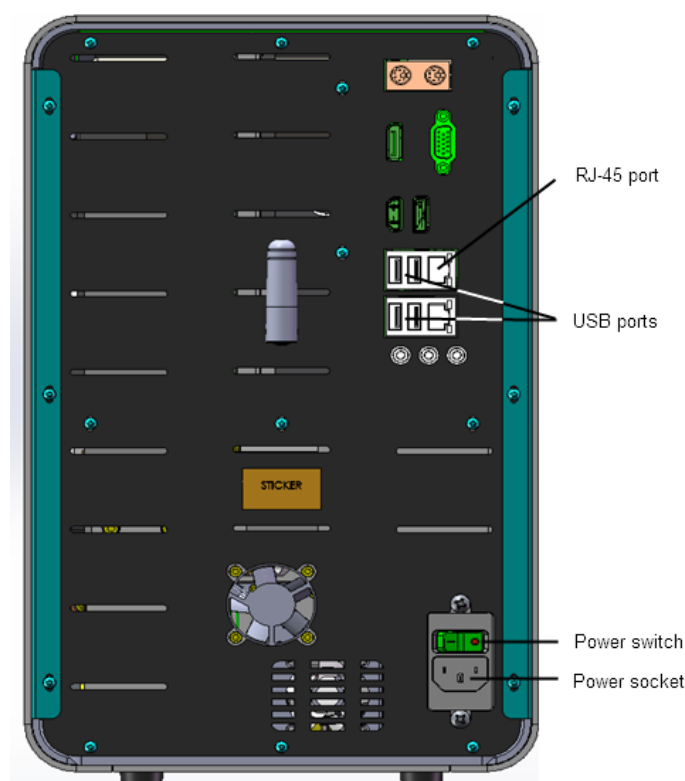


**Figure 1. Rear of Accellix Unit**

4. Connect the bar-code reader to a USB port at the rear of the Accellix unit.
5. Optionally, connect an Ethernet network cable to the RJ-45 port at the rear of the Accellix unit. This enables connectivity to a network. Alternatively, connect a local printer to one of

the USB ports on the rear of the device if Internet is available to the device so the printer's driver can be downloaded.

See Maintenance section regarding connecting to a network or installing drivers.

6. Optionally, connect a keyboard (not supplied) to a USB port on the rear of the unit. This is not mandatory because you can use the device on-screen keyboard.
7. Turn on the device by switching the Power switch at the rear of the unit to ON.

The following message appears on screen:



**Figure 2. System Self Check**

8. Verify that the system completes initialization, and the Home page appears:

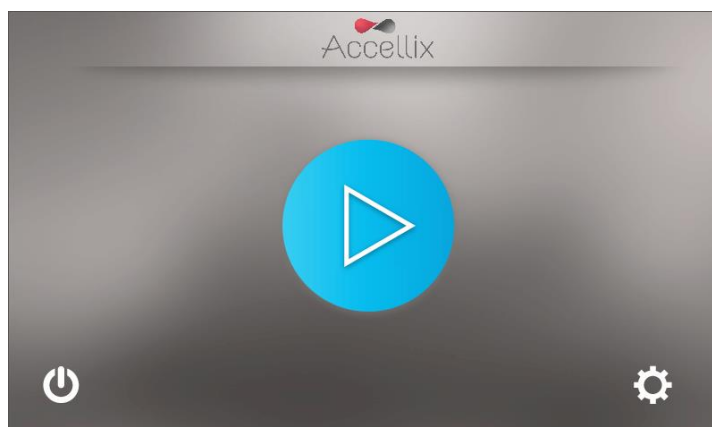


**Figure 3. Home Page**

9. Tap Settings  to access the Settings page.

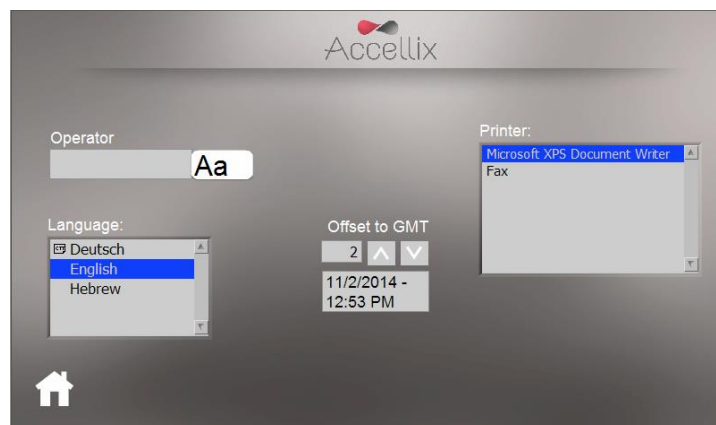


**Figure 4. Settings Page**

10. In the Settings page, perform the following:

- Enter the Operator name in the **Operator** field. Note that the operator name appears in the Results page, so we recommend you change the operator name if the operator changes.
- Select a language from the **Language** list.
- Set the **GMT Offset** to define the date and time settings. The current time is displayed under the GMT Offset fields.
- Define a **Printer** for print jobs. This defines where printouts are sent.

11. Tap the Home icon  to return to the home page.

The device is now ready for use.

## Using the Accellix Diagnostic Device

The Accellix device diagnoses cells in a sample which could be blood drawn from a patient or growth media (“the sample”). The user inserts the sample into a cartridge which is inserted into the device (please see Instructions For Use (IFU) for the specific cartridge being run).

1. In the Home page, tap .

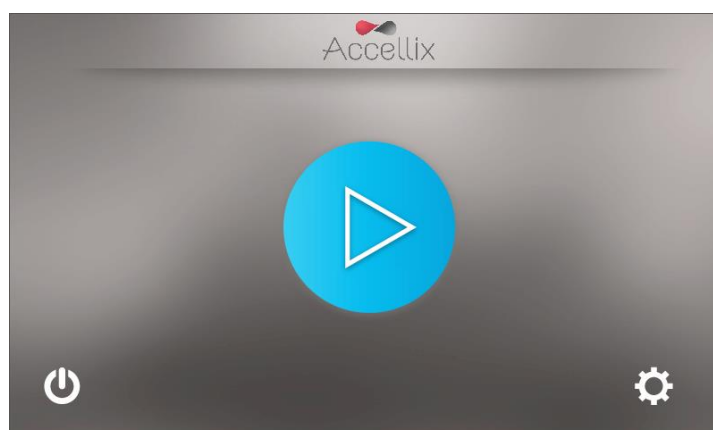


**Figure 5. Home Page**

*The process steps (2 - 7) are displayed by the highlighted gray dots in the bottom of all screens.*

2. Enter the Patient ID by using the bar-code reader, or tapping it in on screen. The Patient ID will be displayed on all screens until cartridge is removed from device.

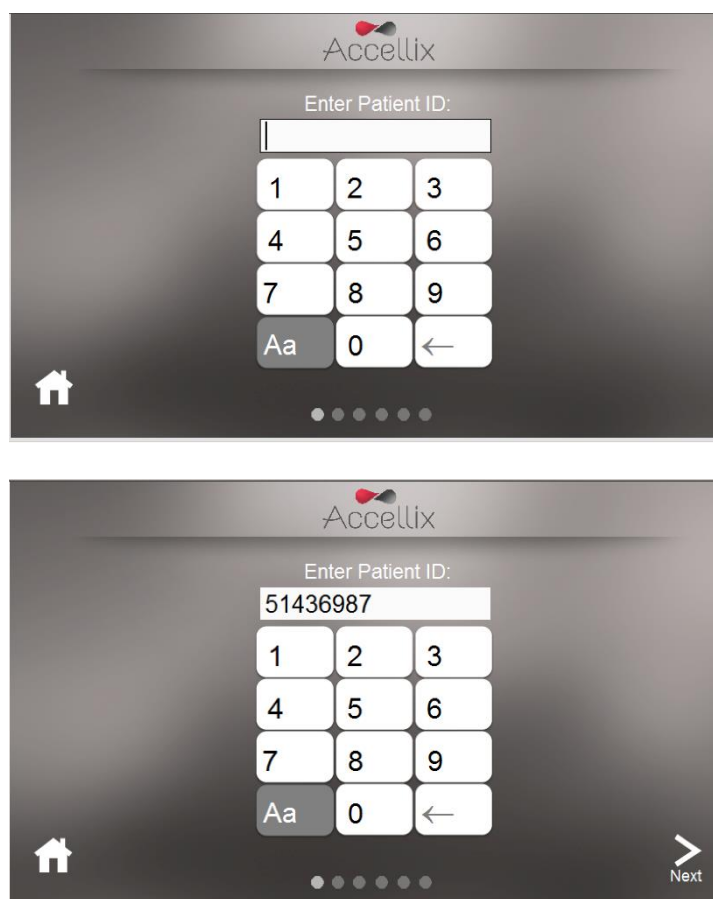


**Figure 6. Entering Patient ID**

3. Tap **Next**.
4. Extract the cartridge from its bag and scan in the cartridge ID using the bar-code reader.
5. When the following screen appears, insert the sample into the cartridge (for further details regarding the sample and the sample loading instructions for a specific test please refer to the Instructions For Use (IFU) for the test being run), and then insert the cartridge into the device.

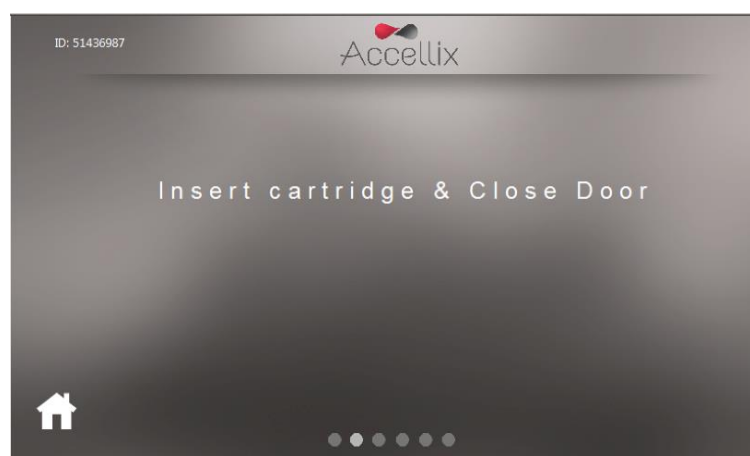


**Figure 6. Instructions How to Insert the Sample and the Cartridge**

6. Wait while the screen displays the following message: “Please wait while cartridge QR code is read and confirmed”.

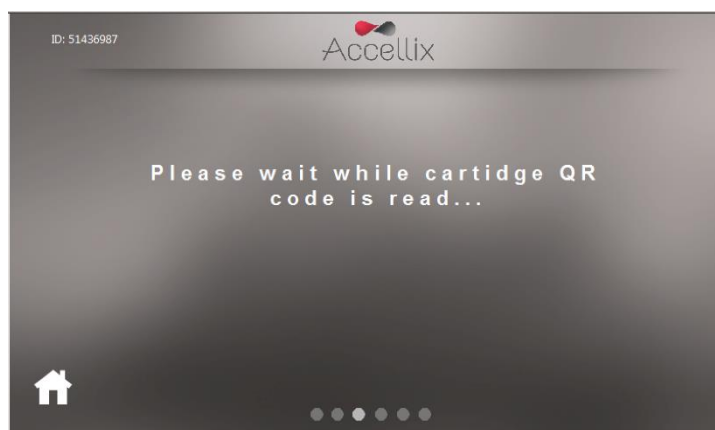


**Figure 7. Instruction to Wait While Cartridge Code is Internally Scanned**

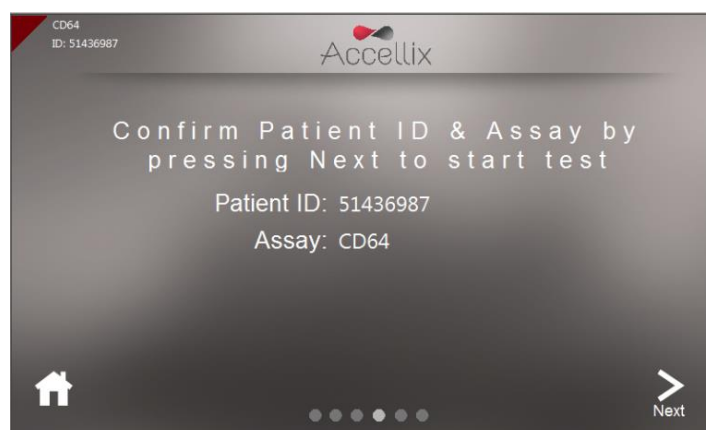


**Figure 9. Instruction to confirm Patient ID and Assay**

7. Tap Next.

While the device processes and analyzes the sample, the following message is displayed. **Take care not to open the door during processing; opening the door will abort the testing process.**

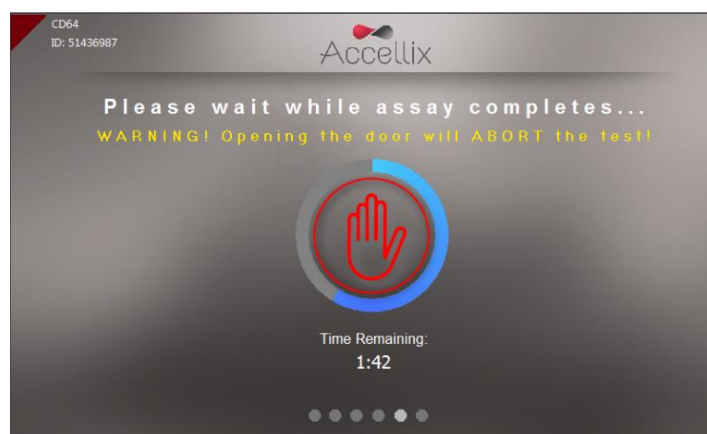


Figure 10. Time to Test End

When processing is complete, a results page appears, similar to the following:



Figure 81. Results Page

8. Tap Next.

(or If desired, tap  to go the page designed print the results. If no printer is connected it will give a message)



**Figure 92. Choosing Printer**

9. Open the door and remove the cartridge when the following message is displayed:



**Figure 13. Instruction to Open Door and Remove Cartridge**

10. Dispose of the cartridge as a biohazard according to local regulations.

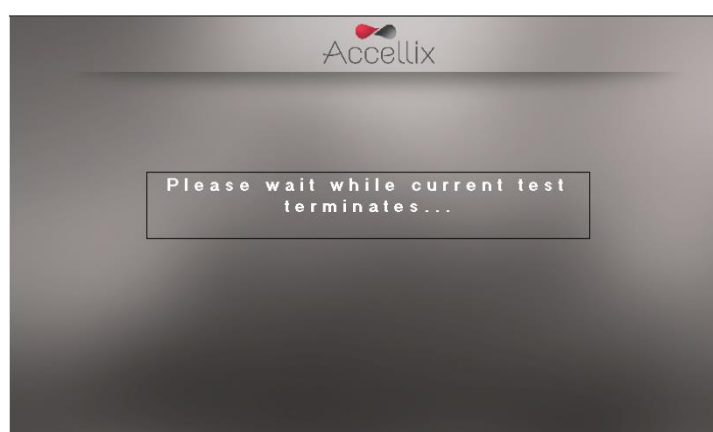


**Figure 14. Shown immediately after an abort or failure.**

It is displayed while the system returns to initial positions so the cartridge can be removed (this can take some time depending on how quickly the assay's script can be aborted and where all the motors are).

## Shutting Down the Device

The device can be left on and there is no need to shut it down regularly. If you do wish to shut it down:

1. In the Home page, tap .

A confirmation query appears.

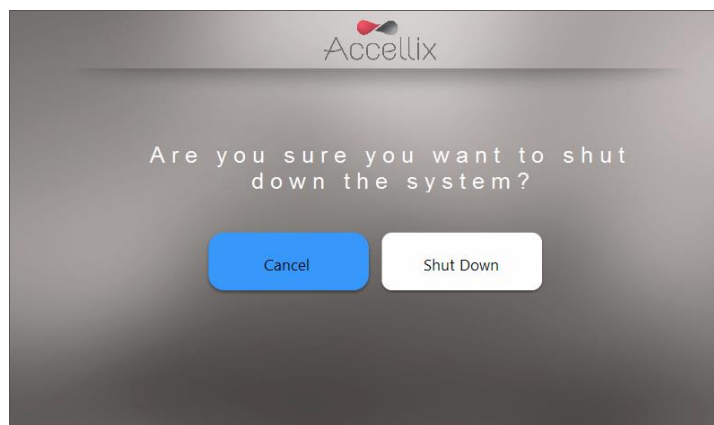


**Figure 15. Shut-Down Page**

2. Tap **Shut Down** to shut down.

To turn the device back on, turn the power switch on the rear of the unit to the OFF position and then turn it back to the ON position.

# Troubleshooting and Maintenance

## Troubleshooting

### Computer Issues

- User should contact service if the system does not start
- User should contact service if the system is out of memory

### Touchscreen Issues

- If touchscreen does not respond the user can operate the system temporarily using a USB connected mouse and keyboard and contact service.

### Internal Instrument Controls and Traceability and Changes in Analytical Performance

The Instrument Controls and Traceability are in place via a set of checks performed upon powering up the instrument, once a day on a fixed schedule if the instrument is not powered down and up once a day and upon the occurrence of a group 2 error (see Error section below). This set of self-checks includes checking the components required to operate the fully automated system. If any such self-check detects a component not functioning properly the user will receive an error message that provides information about the failure and instructions to call service.

Internal assay controls are assay specific and are addressed in the cartridge IFU. They include data controls to verify data integrity and maintained analytical performance per each run.

Traceability: The internal control materials were developed based on a fluorescence bead suspension traceable to the NIST Standard Reference Material SRM 1932 (RM 8640)

## Error Messages

Error Messages are classified in two groups:

**Group 1 errors:** Recoverable errors

**The system detects that an operation failed and it can be recovered.**

Examples of recoverable errors are:

The system does not recognize the cartridge barcode or a patient ID and asks the user to extract the cartridge and insert it again or request the user to enter a patient ID manually. If a certain operation fails repeatedly the system will move to Group 2 error after a certain number of attempts.

Specific instructions for each error type are provided on-screen as in the example below:

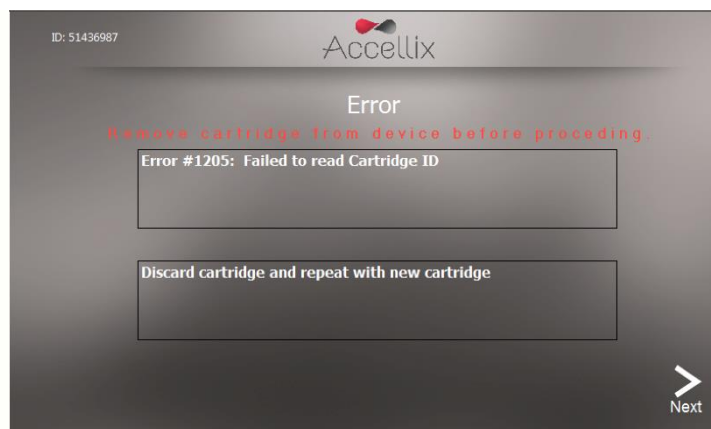


**Figure 16. Example of Group 1 Error Page**

**Group 2 errors:** Recoverable errors requiring instrument self-check

**The system detects that an operation failed but the failure may be connected to a specific cartridge or a specific patient sample.**

Before proceeding with repeating the test with another cartridge the system will provide an error message about which test condition failed and request from the user to perform a self-check. This self-check program is the same automated procedure which is performed by the instrument automatically upon power-up or by automatic scheduling every 24 hours if the system is not powered down once a day. This self-check procedure check a significant number of critical components (such as laser, detectors, cartridge actuation motors and communication between internal components).

Example of cases where the instrument will request the user to reboot the system to perform self-check include:

- Data controls fail
- Laser power is if outside 20% of set-point value
- Average value of image pixel intensity is below control limit
- Acquired file size after acquisition is complete is within +/-10% of control criteria

If the self-check is completed successfully, the system will request from the user to run another cartridge (with the same or a new sample). The system may still provide an error message but it could be related to a specific sample that cannot be measured for the test being run (Please refer to cartridge IFU for the specific assays being run which provides details about Test Limitations and Interferences such as sample types and medical conditions that may lead to assay failure).

If the self-check fails, an error message will provide information about which component is failing the self-check test and request the user to contact the manufacturer.

Specific instructions for each error type are provided on-screen as in the example below:



**Figure 17. Example of Group 2 Error Page**

## Handling

- Handle the instrument with care.
- Protect the system from direct sunlight, humidity and dust.
- Environmental operation conditions:  
Ambient Temperature: 15°C - 32°C  
Non Condensing (Max. Rel. Humidity 85%)
- For information on instrument dimensions and power, refer to Appendix A – Technical Specifications

## Control Method

Control methods and means to verify performance within specifications are inherent to the different assay cartridges and respective data processing.

Further information is provided in the Instructions for Use (IFU) provided with each box of assay specific cartridges and available online at [www.leukodx.com](http://www.leukodx.com)

## Maintenance

- Maintenance – the instrument is maintenance free, the user only needs to follow instructions provided by error messages. See Troubleshooting and Error Messages section below.
- This instrument is classified as a Class 1 Laser product, according to IEC-60825-1 edition 3.

The instrument uses internally a 50mW, 488nm Class 3B Laser - The user / customer / technician should never open the instrument.



- Connection to customer LAN, Wi-Fi network, or Printer should be performed by qualified IT personnel. Connection to customers LAN should be with less than 3 meters cable. Please contact LeukoDx service department to obtain information regarding how to perform such operation.
- Cleaning the System — The Accellix cytometer may need to be cleaned from time to time. In order to maintain the integrity of all of the Accellix components the following cleaning procedure can be used: wipe off the device with a cloth or wipe saturated in isopropyl alcohol (IPA) or an isopropyl alcohol mix. Examples of appropriate cleaning solutions include: CaviWipes and Purisept spray and wipes. The device should be cleaned according to the directions provided with the cleaning solution.
- Decontamination – In case of minor spill from a cartridge, proceed with decontamination using alcohol according to your institution handling procedure for materials that have been in contact with blood. All blood products should be treated as if they may potentially contain pathogens.
- Disposal Procedure – The instrument should be disposed of according to local regulations in place for electronics and medical equipment. Dispose of used cartridges as a biohazard according to local regulations.
- Service Manual – No servicing is to be performed at the user site. All servicing is performed at the manufacturer site according to manufacturing and re-work procedures. For servicing, see Manufacturer information in the beginning of this document, or see contact details at [www.leukodx.com](http://www.leukodx.com).
- Shipment for service – In case shipment for service is required please contact the EU representative or the manufacturer. The original packaging is to be saved and stored in a safe place to enable its re-use for shipping back to the manufacturer for service. In case you consider the instrument to be contaminated please put the instrument in the provided biohazard bag inside the original packaging.

## Cartridge and Assay Specific Issues

Cartridge and Assay Specific issues are specific for each assay run on the instrument and are provided in the Instructions for Use (IFU) provided with each box of assay specific cartridges and available online at [www.leukodx.com](http://www.leukodx.com).

The cartridge IFU for each assay provides information about:

- Measurement Procedure Details
- Cartridge and Assay Specific Internal Controls and Traceability and Changes in Analytical Performance

The Cartridge and Assay Specific and Traceability and Changes in Analytical Performance are also addressed by the instrument by checking that the data generated in a particular run

meets a certain number of data quality checks. Further information is provided in the Instructions for Use (IFU) provided with each box of assay specific cartridges.

- Calibration – The instrument self-checks ensure that the functionality of the instrument is tested. If calibration is required for a certain cartridge or assay type, the details of the nature and frequency of the calibration needed to ensure that the device operates properly and safely will be described in the IFU for such cartridge.

## Appendix A – Technical Specifications

| Instrument Description                         | Specification                                                                                                                                                                                                                                                                                                                   |
|------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Device Dimensions                              | 38 x 23 x 50 cm, 20kg                                                                                                                                                                                                                                                                                                           |
| Power                                          | 100-220V AC 50/60Hz                                                                                                                                                                                                                                                                                                             |
| Use conditions                                 | Ambient Temperature: 15°C - 32°C<br>Non Condensing (Max. Rel. Humidity 85%)<br>Protect the system from direct sunlight, humidity and dust.                                                                                                                                                                                      |
| Excitation Laser                               | 488nm Blue (50mW)                                                                                                                                                                                                                                                                                                               |
| Fluorescence Detector                          | High performance PMT array (8 Channel)                                                                                                                                                                                                                                                                                          |
| Fluorescence Detection Range                   | 505 – 700nm                                                                                                                                                                                                                                                                                                                     |
| Forward Scatter Detection                      | Si PD. Collection angle 10° - 22°                                                                                                                                                                                                                                                                                               |
| Focus and Alignment of Optical platform        | Real time focus and excitation alignment utilizing proprietary image analysis control algorithm                                                                                                                                                                                                                                 |
| DAQ A/D Resolution, Sampling Rate              | 14 bit, 100 KHz                                                                                                                                                                                                                                                                                                                 |
| Software                                       | LeukoDx custom software running on Windows™ 7 embedded, 64 bit, operating system                                                                                                                                                                                                                                                |
| Assay automation                               | Motor control of 7 assay motors: Auto-focus, Auto-alignment, Three reagent injection, Sample Mixing, Sample Reading.                                                                                                                                                                                                            |
| Test Specific Cartridge Description            | Specification                                                                                                                                                                                                                                                                                                                   |
| Cartridge Dimensions                           | 7.1 x 9.7 x 1.2 cm                                                                                                                                                                                                                                                                                                              |
| Performance Characteristics                    | Assay Specific (see relevant cartridge IFU)                                                                                                                                                                                                                                                                                     |
| Sample Carryover                               | None due to single use of cartridge                                                                                                                                                                                                                                                                                             |
| Sample type, Sample volume, Sample Limitations | Assay Specific (see relevant cartridge IFU)                                                                                                                                                                                                                                                                                     |
| Cuvette material                               | Cyclic Olefin Copolymer (COC)                                                                                                                                                                                                                                                                                                   |
| Assay automation                               | Assay Specific: General capabilities are: Three reagent injection steps (one temperature controlled. Each step enables mixing and incubation time, automated sample reading. Assay specific integrated positive and negative controls and data quality checks. Automated data analysis providing the user with a final results. |

## Appendix B – Symbols

### 1. Index of Symbols:



CE Mark



DO NOT REUSE



USE BY



BATCH CODE



MANUFACTURER



EU Representative



IN VITRO DIAGNOSTIC MEDICAL DEVICE



UPPER AND LOWER TEMPERATURE LIMITS



CONSULT INSTRUCTIONS FOR USE



BIOLOGICAL RISKS

## Appendix C – Safety Information

- Do not open the device door while the device is processing a sample as it will abort the test. This is done to protect the user while the laser is active.
- For cartridge and assay specific safety issues please refer to the cartridge IFU.
- Dispose of the cartridge as a biohazard as per local regulations.
- Electrical safety: The instrument meets:
  - IEC/EN 61010-2-101: 2002 (ed.1)  
Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
  - IEC/EN61010-1: 2010
  - EN61326 EMC emission and immunity requirements